

(iv) Operates at the rated capacity, performance, and reliability as specified by the manufacturer;

(v) Contains control and monitoring equipment that operates correctly;

(vi) Was installed in accordance with the technical installation specification of the manufacturer for all tests; and

(vii) Was used to treat volumes and flow rates of ballast water during the shipboard tests consistent with the normal ballast operations of the vessel.

(b) Executive summary.

(c) Introduction and background.

(d) Description of the BWMS.

(e) For each test conducted, summary descriptions of—

(1) Test conditions;

(2) Experimental design;

(3) Methods and procedures; and

(4) Results and discussion.

(f) Appendices, including—

(1) Complete Test Plans for land-based, shipboard, and component tests, for which an EPA Environmental Technology Verification (ETV) Verification Report produced in accordance with the ETV Protocol can substitute for the land-based test plan;

(2) Manufacturer supplied Operation, Maintenance, and Safety Manual that meets the requirements of §162.060–38 of this subpart;

(3) Data generated during testing and evaluations;

(4) Quality Assurance and Quality Control records;

(5) Maintenance logs;

(6) Relevant records and tests results maintained or created during testing;

(7) Information on hazardous materials, active substances, relevant chemicals, and pesticides as detailed in paragraph (g) of this section; and

(8) Permits, registrations, restrictions, and regulatory limitations on use.

(g) The Test Report for a BWMS that may incorporate, use, produce, generate as a by-product and/or discharge hazardous materials, active substances, relevant chemicals and/or pesticides during its operation must include the following information in the appendix of the Test Report:

(1) A list of each active substance or preparation used in the BWMS. For each active substance or preparation that is a pesticide and is not generated

solely by the use of a device onboard the same vessel as the ballast water to be treated, the appendix must also include documentation that the sale or distribution of the pesticide is authorized under the Federal Insecticide, Fungicide, and Rodenticide Act for use for ballast water treatment. For all other active substances or preparations, the appendix must include documentation of the assessment specified in §162.060–32(b) of this subpart.

(2) A list of all hazardous materials, including the applicable hazard classes, proper shipping names, reportable quantities as designated by 40 CFR 117.1, and chemical names of all components.

§ 162.060–36 Quality Assurance Project Plan (QAPP) requirements.

The approval testing and evaluation process must contain a rigorous Quality Assurance and Quality Control program consisting of a QAPP developed in accordance with ISO/IEC 17025:2005(E), as amended ISO/IEC 17025:2005/Cor.1:2006(E) (incorporated by reference, *see* §162.060–5). The independent laboratory performing approval tests and evaluations is responsible for ensuring the appropriate Quality Assurance and Quality Control procedures are implemented.

§ 162.060–38 Operation, Maintenance, and Safety Manual (OMSM).

(a) Each OMSM must include the following sections:

(1) Table of contents.

(2) Manufacturer's information.

(3) Principles of ballast water management system (BWMS) operation, including—

(i) A complete description of the BWMS, methods and type(s) of technologies used in each treatment stage of the BWMS;

(ii) The theory of the BWMS' operation;

(iii) Any process or technology limitations of the BWMS;

(iv) Performance ranges and expectations of the system; and

(v) A description of the locations and conditions for which the BWMS is intended.

(4) Major system components and shipboard application, including—